Response to Applicant's Amendment

1a. The amendment filed on 03 March 2008 has been entered.

Status of Claims:

1b. Claims 1-20 have been cancelled. Thus, claims 21-24 are pending and under consideration.

Response to Applicant's Argument:

2. The following rejections are withdrawn in light of Applicants' arguments:

I. The rejection of claims 21-24 made under 35 U.S.C. 102(b) as being anticipated by Li et al (U.S. Patent 3,853,833) is withdrawn, because the amended claims 21-24 do not encompass the anticipated growth hormone. The amended claims encompass a method of treatment by administering the recited dosages of growth hormone. Thus, while the claims encompass a method of using growth hormone, they do not encompass growth hormone as a product. Accordingly, the Li et al reference does not anticipate the amended claims.

New Necessitated Rejections by Applicant's Amendment:

Claim Rejections Under 35 U.S.C. § 112, first paragraph:

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 21-24 are under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for a method of a method of treating inflammation in a joint of a patient comprising the step of injecting to the joint of said patient a single

dosage of an anti-inflammatory composition comprising an amount of purified growth hormone of between about 0.025 to 0.249 milligrams per kilogram of the patient's body weight, wherein said purified growth hormone is dissolved in a buffer solution to a concentration of between about 5.0 to 7.0 milligrams of said purified growth hormone per milliliter of said buffer solution, does not reasonably provide enablement for a method of treating "all possible diseases" by administering the recited doses of growth hormone. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, practice the invention commensurate in scope with these claims.

Since a specific disease to be treated is not recited in the claims, claims 21-24 are interpreted as being drawn to method of treatment of “all possible” diseases, by administering to a patient a single dosage of purified growth hormone in of between 0.025 to 0.249 milligrams per kilogram. In the declaration filed on 27 August 2007, Applicant submitted that a single intra-articular injection of purified growth hormone at dosages and concentrations of 0.025 to 0.249 milligrams per kilogram of body weight, administered at concentrations of about 5.0 to 6.0 milligrams per milliliter of buffer solution was effective in reducing and/or eliminating signs of inflammation, including pain, swelling, heat, and stiffness in the treated patients. Applicant further added that patients that received this lower dosage did not suffer from side effects, (such as elevated levels of glucose and headaches), that were associated with higher dosages of 0.25 to 0.75 milligrams per kilogram. Accordingly, the instant invention is only enabling for a method of treating inflammation in a joint comprising the step of injecting to the

joint of said patient a single dosage of purified growth in the recited amounts. However, the instant specification fails to teach that the recited dosages of growth hormone are effective in treating any other condition, other than inflammation in a joint. Claims 21-24 broadly encompass method of treatment of any disease by administering the recited dosages of growth hormone, without providing any guidance to indicate that these dosage would treat "all possible" diseases.

The criteria set forth in Ex parte Forman (230 USPQ 546 (Bd. Pat. App. & Int. 1986), and reiterated in In re Wands (858 F.2d 731,737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)), which include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and (8) the breadth of the claims, is the basis for determining undue extermination. In the instant application, the specification fails to establish that the recited dosages of growth hormone would be effective in treating all and any disorder or disease. While the specification teaches that injecting to the joint of a patient a single dosage of purified growth hormone of between about 0.025 to 0.249 milligrams per kilogram, reduces and/or eliminates signs of inflammation, including pain, swelling, heat, and stiffness in the patients treated, the skilled artisan cannot extrapolate that this dosage would treat all and any disease. Therefore, it is unpredictable whether said dosage of growth hormone would be useful in treating all and any disease or condition.

Therefore Applicants have not presented enablement commensurate in scope with instant claims 21-24.

Conclusion:

5. No claim is allowed. Claims are free of prior art of record.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Advisory Information:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia M. Hamud whose telephone number is (571) 272-0884. The examiner can normally be reached on Monday-Friday: 8:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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05 June 2008

/Bridget E Bunner/

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